

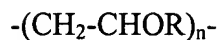
Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1. (original) A formulation of a therapeutic substance suitable for delivery to a patient by a metered dose inhalation device, the formulation comprising a substantially dry powder preparation of the substance in association with a stabilising amount of a glycoside and a polyhydroxylated polyalkene in combination with one or more propellants therefor, wherein the therapeutic substance is selected from peptides and proteins.
2. (original) A formulation according to claim 1, further comprising a cosolvent for said substance.
3. (currently amended) A formulation according to ~~any preceding~~ claim 1, wherein the therapeutic substance is selected from antibodies, interferons, enzymes, hormones, euprolide acetate, CFTR, and  $\alpha$ 1-antitrypsin.
4. (original) A formulation according to claim 3, wherein the therapeutic substance is a hormone selected from insulin, LHRH, granulocyte-colony stimulating factor, calcitonin, heparin, human growth hormone, and parathyroid hormone.
5. (original) A formulation according to claim 1, wherein the substance is dnase I.
6. (currently amended) A formulation according to ~~any preceding~~ claim 1, which is non-immunogenic.

7. (currently amended) A formulation according to ~~any preceding~~ claim 1, which is capable of being stored at room temperature without losing more than 50% biological activity of the therapeutic substance after two months.
8. (currently amended) A formulation according to ~~any preceding~~ claim 1, wherein the glycoside comprises at least one oligosaccharide.
9. (original) A formulation according to claim 8, wherein the glycoside comprises at least one disaccharide.
10. (original) A formulation according to claim 9, wherein the disaccharide is selected from trehalose, mannitol, sucrose, and mixtures thereof.
11. (currently amended) A formulation according to ~~any preceding~~ claim 1, wherein the glycoside constitutes between about 30% and 400% by weight of the therapeutic substance.
12. (currently amended) A formulation according to ~~any preceding~~ claim 1, wherein the propellant is alkane based.
13. (original) A formulation according to claim 12, wherein the propellant is at least one haloalkane.
14. (original) A formulation according to claim 13, wherein the propellant is selected from HFA-134a and HFA-227.
15. (currently amended) A formulation according to ~~any preceding~~ claim 1, wherein at least one polyhydroxylated polyalkene has the general structure



where R is the same or different from one monomeric unit to the next, and is hydrogen, lower alkyl, lower alkenyl, lower alkanoyl, lower alenoyl or is a bridging group between adjacent monomers.

16. (original) A formulation according to claim 15, wherein, when R is not hydrogen, the number of carbon atoms, excluding any  $-\text{CO}-$  group, is between 1 and 6, inclusive.

17. (currently amended) A formulation according to claim 15 ~~or 16~~, wherein the polyhydroxylated polyalkene is selected from polyvinylalcohol, polyvinylacetate, polyvinyl alcohol-*co*-vinyl acetate, poly(vinyl butyral), poly(vinyl alcohol-*co*-ethylene), and mixtures thereof.

18. (original) A formulation according to claim 17, wherein the polyhydroxylated polyalkene is PVA.

19. (currently amended) A formulation according to claim ~~17 or~~ 18, wherein the PVA a hydrolysate of PVAc, the level of hydrolysis being between 40% and 100%.

20. (currently amended) A formulation according to claim ~~17 or~~ 18, wherein the PVA a hydrolysate of PVAc, the level of hydrolysis being between 50 and 90%.

21. (currently amended) A formulation according to ~~any of claims 17 to 20~~ claim 18, wherein the PVA has a molecular weight of between about 9 kDa and 50 kDa.

22. (currently amended) A formulation according to ~~any preceding claim~~ claim 1, wherein the polyhydroxylated polyalkenes are present in an amount of from about 5% to about 200% by weight of the therapeutic substance.

23. (original) A formulation according to claim 22, wherein the polyhydroxylated polyalkene is present between about 10% and about 50% by weight of the substance.

24. (currently amended) A method for the preparation of a formulation as defined in ~~any preceding claim~~ claim 1, comprising blending the therapeutic agent with the glycoside and polyhydroxylated polyalkene substances in an aqueous vehicle, drying the resulting blend to a powder, and then formulating with propellant.

25. (original) A method according to claim 24, wherein the aqueous vehicle is selected from saline, a suitable buffer, and deionised water.

26. (currently amended) A method according to claim 24 ~~or 25~~, which comprises spray—drying the blend.

27. (currently amended) A powdered formulation of a therapeutic agent, a glycoside and a polyhydroxylated polyalkene, as defined in ~~any of claims 1 to 23~~, which is suitable for incorporation with a haloalkane propellant for dispensing from a metered dose inhaler.

28. (original) A powdered formulation according to claim 27, wherein the powder particles have an aerodynamic diameter of between about 1 $\mu$ m and 50 $\mu$ m.

29. (currently amended) A metered dose inhalation device provided with a reservoir comprising a formulation according to ~~any of claims 1 to 23~~ claim 1.